

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system.*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature

graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.*—(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.* (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only—

- (i) A qualified anesthesiologist;
- (ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
- (iii) A doctor of dental surgery or dental medicine;
- (iv) A doctor of podiatric medicine;
- (v) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;
- (vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or
- (vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthesiologist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) *Standard: State exemption.* (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medi-

cine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation—*(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

- (i) The utilization of CAH services, including at least the number of patients served and the volume of services;
- (ii) A representative sample of both active and closed clinical records; and
- (iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

- (1) All patient care services and other services affecting patient health and safety, are evaluated;
- (2) Nosocomial infections and medication therapy are evaluated;
- (3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;